

The Amendments

In the Specification:

Amend the paragraph starting at page 47, line 1:

The normalization of p16^{INK4a} protein levels in solubilized patient samples with respect to a normalization marker characteristic for the presence of epithelial cells allows to assess diagnosis of dysplasias from the samples. The normalization in the present case allows especially to avoid false negative results due to inadequate sampling (for example total amount of patient material not sufficient to perform analysis, or the patient material is not taken at the correct anatomical location). The normalization is carried out in the testing format by applying a threshold value for the OD for the gamma-Catenin normalization marker determined in the ELISA above which the sample is to be classified as adequate. Below a certain threshold (corresponding to 200.000 squamous ectocervical cells) the sample does not contain an adequate amount of patient material. The use of a second normalization marker indicating the presence of endocervical cells provides further information about the adequacy of the sample. The normalization is carried out in the testing format by applying a threshold value for the OD for the Ep-Cam normalization marker determined in the ELISA above which the sample is to be classified as adequate. Below a certain threshold (corresponding to 2000 columnar endocervical cells) the sample does not contain an adequate amount of endocervical cells. (It must be understood that the threshold value applied in this example are adjusted to the particular reaction conditions. The value for the cells as well for OD may vary depending ~~to~~ on the reaction conditions. Thus the values herein are intended to exemplify the conditions and not to limit the scope of the invention. Those of skill in the art know how an appropriate threshold value for a particular test format may be established.) The presence of endocervical cells provides the information that the swab or brush has had contact with the columnar epithelium of the endocervix and thus hints to a contact of the swab or brush with the transformation zone, where cervical dysplasia usually originates. In particular the detection of a certain amount of ectocervical cells (gamma-catenin) together with a certain amount of endocervical cells (Ep-Cam) provides with a high probability the information that the patient material was taken at the correct anatomical location (cervical transformation zone).